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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,838	06/13/2005	Paolo Lombardi	40359/GM/p	5659
7590 Modiano & Associati Via Meravigli 16 20123 Milano - Italy Europe, ITALY				
			EXAMINER	
			CHONG, YONG SOO	
			ART UNIT	PAPER NUMBER
			1627	
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			02/24/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/538,838

Applicant(s)

LOMBARDI, PAOLO

Examiner

Yong S. Chong

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/22)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 11/25/09. Claim(s) 1-8 have been cancelled. Claim(s) 9-13 are pending. Claim(s) 9 and 13 have been amended. Claim(s) 9-13 are examined herein.

Applicant's amendments have rendered the claim objection, 112, 102, and 103 rejections of the last Office Action moot, therefore hereby withdrawn. The following new rejections will now apply.

Application Formalities

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. Applicant is required to file an abstract.

Response to Arguments

The abstract supplied in the response filed on 11/25/09 does not meet the requirements of 37 CFR 1.72(b), specifically where the separate sheet must be entitled "abstract."

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,670,534 in view of Martini et al. (US Patent 5,712,260). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite the treatment of endoparasitosis in an animal by administering a compound of formula I. Although the referenced claims do not recite a combination with cyclodextrin, it is obvious to combine cyclodextrin with the composition taught by the referenced claims. This obviousness rejection is the same as the 103(a) rejection below, therefore the same rationale will be used.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 9-10, 12 are rejected under 35 U.S.C. 103(a) as being obvious over Animati et al. (US Patent 5,670,534, of record) in view of Martini et al. (US Patent 5,712,260).

The instant claims are directed to a method of treating endoparasitosis in an animal by administering a compound of formula I, where n is an integer from 1 to 4, R is NR₃R₄, R₃ and R₄ is H, A is -CONH-Z, Z is ethylene, and R₁ is -C(=NH)-NH₂ in combination with a cyclodextrin.

Animati et al. teach a method of treating diseases caused by parasites, for example, plasmodia, in humans by administering the antiparasitic agent of formula I, where n is an integer from 1 to 4, R is NR₃R₄, R₃ and R₄ is H, A is -CONH-Z, Z is ethylene, and R₁ is -C(=NH)-NH₂ (claims 1-7). The preferred embodiment is taught in Example 1 as 3-[1-Methyl-4-[1-methyl-4-[1-methyl-4-[1-methyl-4-(carboxyamido)pyrrol-2-carboxyamido]pyrrol-2-carboxyamido]pyrrol-2-carboxyamido]pyrrol-2-carboxyamido]propionamide hydrochloride. Animati et al. also teaches oral administration (col. 10, lines 49-50) in an amount 0.1 to 100 mg, 1 to 4 times per day (claim 7).

However, Animati et al. fail to disclose cyclodextrin.

Martini et al. teach that cyclodextrins are well known cyclic oligosaccharides having a cylindrical cavity shaped structure capable of including various guest molecules. Indeed, one of the most interesting properties is their ability to form inclusion compounds or complexes. This kind of complexation confers new physiochemical properties to drugs, and is extensively used in the pharmaceutical field to improve the solubility and stability of active drug substances. Therefore, as a consequence, their dissolution characteristics and bioavailability are greatly improved (col. 1, lines 6-24).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to combine a cyclodextrin, as taught by Martini et al., with the composition comprising the antiparasitic agent of formula I for treating diseases caused by parasites, as taught by Animati et al.

A person of ordinary skill in the art would have been motivated to combine cyclodextrin with the antiparasitic agent of formula I because: (1) Martini et al. teach that cyclodextrins are well known to form inclusion compounds or complexes with pharmaceutical drugs; (2) This complexation is extensively used in the pharmaceutical field to improve the solubility and stability of active drug substances; and (3) This complexation also results in improved dissolution characteristics and bioavailability. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating diseases caused by parasites by administering a combination of an antiparasitic agent of formula I with a cyclodextrin.

Claim(s) 11 and 13 are rejected under 35 U.S.C. 103(a) as being obvious over Animati et al. (US Patent 5,670,534, of record) in view of Martini et al. (US Patent 5,712,260) as applied to claims 9-10, 12 and further in view of Applicant's admission of the prior art.

The instant claims are directed to a method of treating Coccidiosis in an animal by administering a compound of formula I, where n is an integer from 1 to 4, R is NR₃R₄, R₃ and R₄ is H, A is -CONH-Z, Z is ethylene, and R₁ is -C(=NH)-NH₂ with cyclodextrin.

Animati and Martini et al. teach as discussed above, however, fail to disclose Coccidiosis.

Applicant's admission of the prior art teaches that Coccidiosis is caused by families of numerous intestinal parasites, and that it can develop world-wide in almost all domestic and wild animals, including humans (pg. 5, lines 14-16).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to have treated an animal with Coccidiosis by administering a compound of formula I, where n is an integer from 1 to 4, R is NR₃R₄, R₃ and R₄ is H, A is -CONH-Z, Z is ethylene, and R₁ is -C(=NH)-NH₂ with cyclodextrin.

A person of ordinary skill in the art would have been motivated to treat an animal with Coccidiosis by administering a compound of formula I, where n is an integer from 1 to 4, R is NR₃R₄, R₃ and R₄ is H, A is -CONH-Z, Z is ethylene, and R₁ is -C(=NH)-NH₂ with cyclodextrin because: (1) Animati et al. teach that the compound of formula I,

where n is an integer from 1 to 4, R is NR₃R₄, R₃ and R₄ is H, A is -CONH-Z, Z is ethylene, and R₁ is -C(=NH)-NH₂ is an well-known and potent antiparasitic agent that can treat the diseases that the parasites causes; and (2) Applicant's admission of the prior art teaches that Coccidiosis is a well-known disease in animals caused by families of numerous intestinal parasites. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating Coccidiosis in an animal by administering a compound of formula I, where n is an integer from 1 to 4, R is NR₃R₄, R₃ and R₄ is H, A is -CONH-Z, Z is ethylene, and R₁ is -C(=NH)-NH₂ with cyclodextrin.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong S. Chong/
Primary Examiner, Art Unit 1627

YSC